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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/432,881	11/02/1999	MICHELINE MARKEY	15662-000900	1727

20350 7590 03/17/2003

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EXAMINER

WEBMAN, EDWARD J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 03/17/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.	09/432881	Applicant(s)	MARKEY
Examiner	WEBBMAN	Group Art Unit	1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

**Pri d for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

Responsive to communication(s) filed on 12/12/02.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

Claim(s) 1 - 99 is/are pending in the application.

Of the above claim(s) 3-5, 7-13, 19-47, 52-99 is/are withdrawn from consideration. *JW*

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1, 2, 6, 14-18, 48-51 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

**Application Papers**

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119 (a)-(d)**

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

**Attachment(s)**

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892

Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948

Other \_\_\_\_\_

**Office Action Summary**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6, 14-18, 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shell (WO 97/47285, see IDS paper no. 8 filed on July 2, 2001) in view of Acharya (US Patent No. 5,686,094) Sewester et al. (Facts and Comparisons) and Hsiao.

Shell (WO 97/47285) teaches a controlled release composition comprising an active drug and a solid matrix which swells or expands upon contact with gastric fluid in the fed mode (see page 4, line 32).

Shell does not teach an active drug docusate.

Acharya teaches docusate as a laxative (see column 7, lines 39, 57-58 and column 8, line 6). Controlled release is disclosed (see column 5, line 44).

Hydroxypropyl cellulose is specified (see column 5, lines 53-54).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to add docusate to the composition of Shell to achieve the beneficial effect of an additional laxative treatment in view of Acharya.

As to the claimed amount of docusate, it is well known in the art that the therapeutic range of docusate is within the claimed invention (see Facts and Comparisons, page 322a).

Applicants argue Docusate is a drug which should be released in the colon not the stomach. However, Hsiao teaches a device for release of drugs in the stomach, like Shell. (column 2 lines 48-52). Docusate is disclosed (column 7 lines 1-2). Clearly, then, delivery of the Acharya Docusate in the stomach-releasing vehicle of Shell as a Laxative would be recognized by one with ordinary skill as a workable combination in view of the Hsiao Disclosure.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday to Friday 9 Am 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Webman/LR  
February 25, 2003

  
EDWARD WEBMAN  
FEBRUARY 25, 2003  
2003-1393